

**Navajo Nation Human Research Review Board
Institution Review Board Meeting Agenda**

DATE: November 21, 2017, 9:00 AM

PLACE: NDOH West Conference Room,
Window Rock, AZ

MEMBERS:

Dr. Mark C. Bauer, PhD. - Scientific Education
Beverly Becenti-Pigman, Chairperson – Community
Dr. David Begay, PhD. - Scientific Education
Dr. Raymond Reid, MD - Medicine
Rebecca Izzo-Manymules, MPH, *PhD. (C)* - Education
Ursula Knoki-Wilson, MSN, MPH – Nursing
Wallace McGilbert – Community
Dr. Calvin White, PhD. - Scientific Education
Mike Winney, Staff Member

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation
 - Introductions:
- III. Review and Approval of Agenda:
- IV. Review and Approval of September 19, 2017 Meeting Minutes:

NEW BUSINESS:

- V. Quarterly Report:
- VI. Serious Adverse Events (SAEs)
- VII. New Presentations:
- VIII. Returning Presentations:
- IX. Noon Hour Discussion: Dine College Policy Institute
- NNHRRB Research Analysis Report.
- X. Manuscripts / Abstracts to submit NNHRRB Application:
- XI. Announcements / Adjournment:

Navajo Nation Human Research Review Board
IRB Meeting Agenda

SERIOUS ADVERSE EVENTS:

1. NNR-02.110 PI: Knowler, William MD *TABLED ITEM Use Packet item from October 17, 2017 Meeting*
Diabetes Prevention Program Outcomes Study (DPPOS)
2. NNR-16.264 PI: Reid, Raymond M.D.
Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months.

NEW PRESENTATION(S)

1. NNR-17.287T PI: Sehn, Hannah *TABLED ITEM Use Packet item from October 17, 2017 Meeting*
Understanding the Structural Barriers and Opportunities to Improve Cancer Treatment on Navajo Nation
Reason on New
Description: Request Review and Approval of New Study (No Harvard IRB, Need GIMC Approval, Need Audio Consent Form)
2. NNR-17.290T PI: Tayah, Roberta *TABLED ITEM Use Packet item from October 17, 2017 Meeting*
Family Stories: How Homes and Schools Influence and Navigate Career Pathways form Navajo High School Students
Reason on New Title
Description: Request Review and Approval of New Study (No presenter)
3. NNR-17.291T PI: Lance, Peter FRCP
Reason on New Title
Description: Request Review and Approval of New Study

RETURNING PRESENTATION(S)

1. NAR-96.013 PI: Santosham, Mathuram MD
Epidemiology and Immunology of Respiratory Syncytial Virus Infections in Navajo and Apache Infants.
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period.
2. NNR-01.085 PI: Reid, Raymond M.D.
Effect of Pneumococcal Conjugate Vaccine on Nasopharyngeal Colonization among Adult Household Contacts of Vaccinated
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

3. NNR-02.099 PI: Santosham, Mathuram MD
Safety and Efficacy of Pentavalent (G1, G2, G3, G4, and P1) Human-Bovine Reassortant Rotavirus Vaccine in Healthy Infants
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
4. NNR-02.111 PI: Reid, Raymond M.D.
Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
5. NNR-05.174 PI: Reid, Raymond M.D.
In-home Prevention of Substance Abuse Risk in Navajo Teen Families
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
6. NNR-06.195 PI: Deaton, James
National Indian Education Study 2007
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 15 - October 13, 2017 period
7. NNR-09.253 PI: Reid, Raymond M.D.
Impact of 13-valent pneumococcal conjugate vaccine (PVC13) on pneumococcal disease and colonization among Native American communities
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
8. NNR-09.255 PI: Reid, Raymond M.D.
Pilot Study of the Association between Acute Gastroenteritis and Water Quality, Availability, and Handling Practices on the Navajo Nation
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
9. NNR-09.259 PI: Santosham, Mathuram MD
Menu for Life - Assessing Food Security Risk among At-Risk Southwestern Native Americans
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
10. NNR-11.342 PI: O'Connell, Joan M. Ph.D.
Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 16 - August 15, 2017 period
11. NNR-11.346 PI: Reid, Raymond M.D.
Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

12. NNR-14.179 PI: Jordan, Shawn Ph.D.

Engineering Design Across Navajo Culture, Community and Society

Reason on Quarterly Review

Description: Request Review and Acceptance of 2 Quarterly Reports covering 1) May 21 - August 20, 2017; 2) August 21 - November 20, 2017 periods

13. NNR-15.199 PI: Shin, Sonya MD

REACH for Healthy Navajo Communities.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 17 - September 17, 2017 period

14. NNR-15.212 PI: Solomon, Mark G.

2015 Safety Belt Use Estimates for the Indian Nations.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

15. NNR-15.232 PI: Hammitt, Laura M.D.

Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

16. NNR-16.261 PI: Hammitt, Laura M.D.

Evaluation of maternal immunization and interventions to increase uptake of vaccines among expectant American Indian women

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period.

17. NNR-16.251 PI: Frank, Daniel MS

Investigating Culturally-Contextualized Making with the Navajo Nation

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 19 - October 19, 2017 period

18. NNR-16.238 PI: Hammitt, Laura M.D.

Active Bacterial Surveillance for Staphylococcus aureus on the Navajo and White Mountain Apache Reservations.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

19. NNR-16.244 PI: Bauer, Mark C. Ph.D

Identifying and Reinforcing Positive Behaviors among Dine' College Students

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) October 20, 2016 - January 19, 2017; 2) January 20, 2017 - April 19, 2017 periods

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Reports covering April 19, 2016 - April 19, 2017 period

20. NNR-17.268 PI: Yazzie, Jaime O. B.S.
Din'e Perceptions and Concerns of Ecosystem Services under Climate Change
Reason on Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering April 1 - September 20, 2017 period.
21. NNR-97.018 PI: Santosham, Mathuram MD
A double Blinded, Controlled Study of the Efficacy, Immunogenicity, Safety and Tolerability, and Effectiveness of a Pneumococcal Conjugate Vaccine Containing 7 Serotypes (6B, 14, 19F, 23F, 18C, 4, and 9V) Compared to a Control Meningococcal C Vaccine in Navajo and Apache Indian Infants
Reason on Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
22. NNR-09.262 PI: Shirley, Valerie J. Ph.D.
Indigenous Subjectivities: Dine' Youth (DE) Construct Identity
Reason on Final Report
 Description: Request Acceptance and Approval to Close Out Study.
23. NNR-15.222 PI: Huyser, Kimberly R. Ph.D.
The American Indian Reservation as a source of Risk and Resilience against Psychological Distress: An Analysis of Two American Indian Tribes
Reason on Final Report
 Description: Request Acceptance and Approval to Close Out Study
24. NNR-16.255 PI: Radovanovic, Sonja D Ph.D., M.A.
First Things First Navajo Regional Partnership Council
Reason on Continuation Request
 Description: Request Acceptance and Approval of Continuation Report covering September 21, 2017 - September 20, 2018 period
25. NNR-16.263 PI: Oren, Eyal Ph.D.
Helicobacter Pylori Infection and Stomach Cancer
Reason on Continuation Request
 Description: Request Acceptance and Approval of Continuation Request covering November 30, 2017 - November 30, 2018 period
Reason on Annual Report
 Description: Request Review and Acceptance of Annual Report covering November 29, 2016 - November 29, 2017 period
26. NNR-02.105 PI: Reid, Raymond M.D.
Epidemiology Study of Pneumonia among Navajo and White Mountain Apache Adults
Reason on Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period
Reason on Continuation Request
 Description: Request Acceptance and Approval of Request for Continuation of Study covering December 17, 2017 - December 17, 2018 period

27. NNR-04.151 PI: Santosham, Mathuram MD

A Phase 3 Study of MEDI-524 (Numax®), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Navajo and White Mountain Apache Infants in the Southwestern United

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 21, 2016 - September 21, 2017 period

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

28. NNR-05.165 PI: Reid, Raymond M.D.

Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report Covering September 6, 2016 – September 6, 2017 period

Reason on Quarter Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 – September 30, 2017 period

29. NNR-07.198 PI: McGrath, Jane W. MD *TABLED ITEM Use Packet from October 17, 2017 Meeting*

Envision New Mexico Pediatric Overweight Learning Collaborative

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March 17 - June 16, 2017 period

Reason on Change in Investigators

Description: Request Acceptance and Approval of Change of Investigator Dr. Kirsten Bennett, PhD, RD, LD. Attachments: Part 5 Certification, IRB Approval Letter, CV.

30. NNR-07.212 PI: Sanderson, Priscilla Ph.D. *TABLED ITEM Use Packet Item from October 17, 2017 Meeting*

A Pilot Investigation of Colorectal Cancer Screening for Awareness, Practices, and Recommendations on the Navajo Reservation

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 1 - August 31, 2017 period

Reason on Annual Report

Description: Request Acceptance and Approval of Continuation Request covering September 16 - August 31, 2017 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 1, 2017 - August 31, 2018 period

31. NNR-07.216 PI: Reid, Raymond M.D.

Rapid-response investigation of pediatric cases of invasive Haemophilus influenzae in Navajo American Children

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 18, 2016 - September 18, 2017 period

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

32. NNR-10.268 PI: Batliner, Terrence DDS

Preventing Caries in Preschoolers: Testing a Unique Service Delivery Model in American Indian Head Start Programs

Reason on Annual Report

Description: Request Acceptance and Approval: 1) Annual Report, 2) Research Summary, 3) Original Protocol Copy, 4) Published Manuscript - A Custer-Randomized, Community Based Tribally Deliver Oral Health Promotion Trial in Navajo Head Start Children, 5) Published Manuscript - Absence of Fluoride Varnish Related adverse Events in Caries Prevention Trails in Young Children, US.

33. NNR-10.287 PI: Gittelsohn, Joel Ph.D.

Multilevel Obesity Prevention Trial for American Indian Community (OPREVENT)

Reason on Conference Presentation

Description: Request Acceptance and Approval of 2 Abstracts (also for NNR-16.245) for Conference Presentations: 1) Participation in Food Assistance Programs and Ardiometabolic Risk Among American Indian Health; 2) Multi-level, multi-component obesity intervention reduces soda intake in American Indian Tribes, at Academy of Nutrition and Diabetic Annual Food and Nutrition Conference and Expo in Chicago on October 2017, and in Maryland on October at Annual Conference for the Obesity

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 19, 2016 - December 19, 2017 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 19, 2017 - December 19, 2018 period

34. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.

Navajo Birth Cohort Study (NBCS)

Reason on Consent Modification

Description: Request Review and Approval of Revised Consent Forms.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

Reason on Other

Description: Request Review and Acceptance of UNM staff to access to Study participant's Medical Records to complete missing medical records abstractions through 1st year participants.

35. NNR-13.113 PI: English, Kevin C. Dr.PH. *TABLED ITEM Use Packet item from October 17, 2017 Meeting*

Tribal FOBT Study

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 21 - August 20, 2017 period

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 21, 2016 - August 20, 2017 period.

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 21, 2017 - August 21, 2018 period

36. NNR-15.213 PI: Quintana, Eugenia

Residential Wood Smoke Intervention Improving Health In Native American Populations

Reason on Consent Modification

Description: Request Review and Approval of Revised Consent Form for 2017-2018 Study Period

37. NNR-15.214 PI: Lewis, Johnnye L. Ph.D.

Wood Stove Interventions and Child Respiratory Infections in Rural Communities

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 21 - October 20, 2017 period

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 20, 2016 - October 19, 2017 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 20, 2017 - October 19, 2018 period, attached UNM IRB approval letter.

38. NNR-15.223 PI: Richards, Jennifer MPH

Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

Reason on Amendment

Description: Request Acceptance and Approval of Amendments to Protocol: 1) add Tuba City, 2) increase sample size by 150, and 2 focus group discussions, 3) Consent Form, 4) Data Collection Instruments

39. NNR-16.234 PI: Chief, Karletta Ph.D.

To Litso, the water is Yellow: Investigating short term exposure and risk perception of Navajo communities to the Gold King Mine toxic spill

Reason on Conference Presentation

Description: Request Acceptance and Approval of Abstracts and Poster for Conference Presentation at American Geophysical Union Conference in New Orleans, on December 11-15

Reason on Conference Presentation

Description: Request Acceptance and Approval of Power Point Presentation at Shiprock, Upper Fruitland and Aneth on December 6-8,

40. NNR-16.245 PI: Gittelsohn, Joel Ph.D.

Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)

Reason on Conference Presentation

Description: Request Acceptance and Approval of 2 Abstracts (also for NNR-10.287) for Conference Presentations: 1) Participation in Food Assistance Programs and Cardiometabolic Risk Among American Indian Health; 2) Multi-level, multi-component obesity intervention reduces soda intake in American Indian Tribes, at Academy of Nutrition and Diabetic Annual Food and Nutrition Conference and Expo in Chicago on October 2017, and in Maryland on October at Annual Conference for the Obesity

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July - September 2017 period

41. NNR-16.249 PI: Melton, Ada Pecos MPA

The National Baseline Study (NBS) Examining Violence Against American Indian and Alaska Native Women Living in Indian Country and Alaska Native Villages.

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 19, 2016 - July 19, 2017 period

42. NNR-16.258 PI: Swaim, Randall C. Ph.D.

Substance use among American Indian Youth attending schools on or near Reservation

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

Reason on Amendment

Description: Request Review and Approval of Protocol Amendments: to add 4 new schools, Hermosa Middle School, Magdalena High School, Shonto Prep Schools, and Tsehootsooi Middle School

43. NNR-16.264 PI: Reid, Raymond M.D.

Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Request for Study Continuation covering December 20, 2017 - December 20, 2018

44. NNR-17.277 PI: Moore, Kelly R M.D.

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Amendment

Description: Request Acceptance and Approval of Amendment of Consent Form and Assent Form for Protocol. Attached Colorado IRB Approval

45. NNR-17.282 PI: Hammit, Laura M.D.

A Study to Evaluate the Efficacy of Maternal Immunization with RSV F vaccine in Preventing RSV Lower Respiratory Tract Infection in Young Infants (RSV-M-302)

Reason on Addendum

Description: Request Review and Acceptance of Updated Investigator Brochure (IB) of Protocol

46. NNR-11.325 PI: Reid, Raymond M.D.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

47. NNR-11.332 PI: Speakman, Kristen, MA, MPH

Evaluation of an Edible School Garden Program; Evaluation of the Feast for the Future Community Visioning Program.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2017 period

Last page and end of Agenda